



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,345	05/29/2001	Yevgeni Yurevich Milanovski	B0192/7026	4651

23628 7590 10/01/2003

WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
----------	--------------

1753

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,345

Applicant(s)

MILANOVSKI ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 and 38 is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Oath/Declaration

1. Applicant's Declaration claims priority under 35 U.S.C. §§119 or 365(a),(b) from United Kingdom application GB98116346; however, the preliminary amendment of May 29, 2001 claims priority from Russian application number 98116346. Also, Russian application number 98116346 has been submitted as a priority document. Applicant is requested to resolve the inconsistency between the priority claimed in the Declaration, on the one hand, and, on the other hand, the priority stated in the specification and, by implication, through the submitted Russian application.

Information Disclosure Statement

2. The references cited in the Search Report of PCT/GB99/02785 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

Specification

3. Claims 8, 28, 29, and 37 are objected to because of the following informalities:
 - a) Claim 8, line 10: the second occurrence of “the” should be deleted (or should “said “ be -- sensing --?);
 - b) Claim 28, line 3: the second occurrence of “the” should be deleted (or should “said “ be -- sensing --?);
 - c) Claim 28, line 9: the second occurrence of “the” should be deleted (or should “said “ be -- sensing --?);
 - d) Claim 29, line 3: the second occurrence of “the” should be deleted (or should “said “ be -- sensing --?); and
 - e) Claim 37, line 9: “molecule” should be -- molecules --.
4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

Art Unit: 1753

a) Claim 1 recites the limitation "treated sensing electrode" in line 20. There is insufficient antecedent basis for this limitation in the claim;

b) Claim 1, line 24: should the sensing electrode in step (e) also be a treated sensing electrode as in step (d)?

c) Claim 1 recites the limitation "said desired analyte" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim;

d) Claim 2 recites the limitation "treated sensing electrode" in line 19. There is insufficient antecedent basis for this limitation in the claim;

e) Claim 2, line 23: should the sensing electrode in step (e) also be a treated sensing electrode as in step (d)?

f) Claim 6 states that secondary receptors *or* competing molecules with a charge label may be used. However, this is inconsistent with claim 1, which requires secondary receptors with a charge label;

g) Claim 7 recites the limitation "treated sensing electrode" in line 20. There is insufficient antecedent basis for this limitation in the claim;

h) Claim 7, line 24: should the sensing electrode in step (e) also be a treated sensing electrode as in step (d)?

i) Claim 8 recites the limitation "said desired analyte" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim;

j) Claim 8 recites the limitation "treated sensing electrode" in line 19. There is insufficient antecedent basis for this limitation in the claim;

Art Unit: 1753

k) Claim 8, line 24: should the sensing electrode in step (e) also be a treated sensing electrode as in step (d)?

l) Claim 15 recites the limitation "receptor *molecules* [emphasis added]" in line 2. There is insufficient antecedent basis for this limitation in the claim;

m) Claim 15: does the recited list of possible receptor molecules also apply to the secondary receptors?

n) Claim 15, line 5: parenthetical elements should be avoided. Are chemical compounds conjugated with "haptens" being claimed?

o) Claim 18 states that secondary receptors *or* competing molecules with a charge label may be used. However, this is inconsistent with claim 1, which requires secondary receptors with a charge label;

p) Claim 20 states that secondary receptors *or* competing molecules may be used. However, this is inconsistent with claim 1, which requires secondary receptors; and

q) Claim 21 recites the limitation "receptor *molecules* [emphasis added]" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Note that dependent claims will have the deficiencies of base and intervening claims.

Allowable Subject Matter

8. Claims 37 and 38 are allowed.

9. Claims 1, 2, 7, and 8 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action.

10. Claims 3-6 and 9-36 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

a) Claims 1 and 7: Steps (d) and (e) each, of claims 1 and 7, require monitoring the electric potential difference between the sensing electrode and a reference electrode.

The McNeil et al. (GB 2276724 A) reference teaches contacting an electrochemical sensing electrode, which comprises first receptors immobilized on a conductive polymer, with a solution comprising secondary receptors capable of binding to the analyte at a site spatially distinct from the site of binding to the immobilized receptors, the secondary receptors being conjugated with a charge label (abstract and penultimate paragraph on page 4). However, current change is monitored in the McNeil et al. reference (last paragraph on page 3 bridging to page 4; Figure 1; and the *Example* on page 5 bridging to page 6), not electric potential

Art Unit: 1753

difference. It would not have been obvious to monitor electric potential instead of current because the label for the secondary receptor, a peroxidase, is especially suited for current measurements with a polarized sensing electrode (last paragraph on page 2);

b) Claims 3-6 and 15-36 depend directly or indirectly from allowable claim 1;

c) Claim 2: Steps (d) and (e) each require monitoring the electric potential difference between the sensing electrode and a reference electrode;

The McNeil et al. (GB 2276724 A) reference teaches contacting an electrochemical sensing electrode, which comprises first receptors immobilized on a conductive polymer, with a solution comprising competing molecules conjugated with a charge label (abstract and last paragraph on page 4 continued onto page 5). However, current change is monitored in the McNeil et al. reference (last paragraph on page 3 bridging to page 4; Figure 1; and the *Example* on page 5 bridging to page 6), not electric potential difference. It would not have been obvious to monitor electric potential instead current of because the charge label, a peroxidase, is especially suited for current measurements with a polarized sensing electrode (last paragraph on page 2);

d) Claim 8: Steps (d) and (e) each require monitoring the electric potential difference between the sensing electrode and a reference electrode;

The McNeil et al. (GB 2276724 A) reference teaches contacting an electrochemical sensing electrode, which comprises first receptors immobilized on a conductive polymer, with a solution comprising competing molecules conjugated with an enzyme (abstract and last paragraph on page 4 continued onto page 5). However, current change is monitored in the McNeil et al. reference (last paragraph on page 3 bridging to page 4; Figure 1; and the *Example*

Art Unit: 1753

on page 5 bridging to page 6), not electric potential difference. It would not have been obvious to monitor electric potential instead of current because the charge label, a peroxidase, is especially suited for current measurements with a polarized sensing electrode (last paragraph on page 9);

e) Claims 9-14 depend directly or indirectly from allowable claim 7;

f) Claim 37 requires the avidin or streptavidin, to which the receptor molecule is attached, to be immobilized in or adsorbed on the electroconductive polymer.

The Taniguchi et al. (US 4,839,017) reference teaches a method of electrochemical detection of an analyte in a sample, the method comprising providing a sensing electrode comprising an electrically conductive polymer to which receptor molecules, for binding to analyte, have been attached (abstract). The Taniguchi et al. reference also teaches monitoring the potential difference between the sensing electrode and a reference electrode (col. 8, ll. 11-16). However, avidin or streptavidin is not disclosed by the Taniguchi et al. reference. Receptor molecules in the Taniguchi et al. reference are attached to the electrically conductive polymer through functional groups such as aldehyde or carboxyl groups on the electrically conducting polymer (col. 3, ln. 43 – col. 4, ln. 5) and

g) Claim 38 depends from allowable claim 37.

Art Unit: 1753

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola

Alex Noguerola

9/17/2003

Primary Examiner

TC1700